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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,548	05/29/2001	Gunnar Grue-Sorensen	P 277978	2538

909 7590 05/29/2003

PILLSBURY WINTHROP, LLP  
P.O. BOX 10500  
MCLEAN, VA 22102

EXAMINER
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BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/29/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/787,548

Applicant(s)

GRUE-SORENSEN ET AL.

Examiner

Barbara P. Badio, Ph.D.

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 6) <input type="checkbox"/> Other:  |

**First Office Action on the Merits**

***Specification***

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

2. Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-8, 17 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims are drawn to the "use" of the claimed compounds. A use is not patentable under 35 USC 101.

Therefore, these claims will not be examined further on the merits.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9-16, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons.

(a) Claim 9 drawn to compounds is dependent on claim 1, which is not a compound claim, for definition of variables. It is suggested that said variables be defined by the instant claims;

<sup>15, 21,</sup>  
m (b) Claims 11-16 do not define formulae I and/or Ia and, thus, they are dependent on the specification for meaning;

(c) Claim 11 contains duplicate recitation of compounds, i.e., compounds 157 and 161 are identical to compounds 159 and 162, respectively; and

(d) Claims 14 and 19 recite the phrases/terms "such as", "preferably", "including", "e.g.", "particularly" etc. Said phrases/terms render the claims indefinite because it is unclear whether the limitations following the phrases/terms are part of the claimed invention.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 9-16, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Calverley et al. (WO 91/15475).

Calverley et al. teach a generic group of vitamin D compounds such as 1(S),3(R)-dihydroxy-20(R)-(3,3-difluoro-4-hydroxy-4-methyl-1-pentyloxymethyl)-9,10-seco-pregna-5(Z),-7(E),10(19)-triene (see the entire article, especially page 1, line 17 – page 2, line 6; Tables 1 and 2; page 54, claim 3, compound h). The reference teaches the compounds are useful in treatment of various disorders including skin ageing hyperparathyroidism, imbalance of the immune system and diabetes mellitus (see page 1, lines 3-16). The compounds, compositions and methods of use taught by the reference are encompassed by the instant claims.

9. Claims 9-16, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Calverley et al. ('629).

Calverley et al. teach a generic group of vitamin D compounds such as 1(S),3(R)-dihydroxy-20(R)-(3,3-difluoro-4-hydroxy-4-methyl-1-pentyloxymethyl)-9,10-seco-pregna-5(Z),-7(E),10(19)-triene (see the entire article, especially col. 1, lines 19-47; Tables 1 and 2; col. 36, claim 3, compound h). The reference teaches the compounds are useful in treatment of various disorders including hyperparathyroidism, skin ageing, imbalance of the immune system and diabetes mellitus (see col. 1, lines 4-

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18). The compounds, compositions and methods of use taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 9-16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calverley et al. (WO 91/15475).

Calverley et al. teach a generic group of vitamin D compounds such as 1(S),3(R)-dihydroxy-20(R)-(3,3-difluoro-4-hydroxy-4-methyl-1-pentyloxymethyl)-9,10-seco-pregna-5(Z),-7(E),10(19)-triene (see the entire article, especially page 1, line 17 – page 2, line 6; Tables 1 and 2; page 54, claim 3, compound h). The reference teaches the compounds are useful in treatment of various disorders including skin ageing, hyperparathyroidism, imbalance of the immune system and diabetes mellitus (see page 1, lines 3-16).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including that of the instant claims, because an ordinary

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artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. The motivation to make additional compounds is based on the desire to obtain additional compounds useful in treatment of the various disorders as taught Calverley et al.

12. Claims 9-16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calverley et al. ('629).

Calverley et al. teach a generic group of vitamin D compounds such as 1(S),3(R)-dihydroxy-20(R)-(3,3-difluoro-4-hydroxy-4-methyl-1-pentyloxymethyl)-9,10-seco-pregna-5(Z),-7(E),10(19)-triene (see the entire article, especially col. 1, lines 19-47; Tables 1 and 2; col. 36, claim 3, compound h). The reference teaches the compounds are useful in treatment of various disorders including hyperparathyroidism, skin ageing, imbalance of the immune system and diabetes mellitus (see col. 1, lines 4-18).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including that of the instant claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. The motivation to make additional compounds is based on the desire to obtain additional compounds useful in treatment of the various disorders as taught Calverley et al.

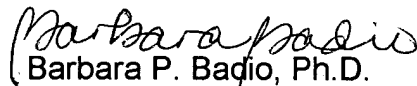
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***Telephon Inquiry***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
May 28, 2003